K110078

FEB 15 2012

5. 510(k) SUMMARY

Submitter:	Nakanishi, Inc. 700 Shimohinata Kanuma-Shi, Tochigi-Ken Japan 322-8666
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Date Prepared:	January 7, 2011
Trade Name:	Cordless Prosthodontic Screwdriver with Torque Calibration System Model iSD900
Common Name:	Handpiece, Direct Drive, AC-Powered
Classification Name:	Handpiece, Direct Drive, AC-Powered
Predicate Device:	K100600 - W&H Prosthodontic Screwdriver IA-400
Device Description:	The Cordless Prosthodontic Screwdriver with Torque Calibration System consists of the cordless motor handpiece, the contra angle head, and the quick charger. The motor handpiece and the contra angle head are connected via a proprietary coupling. The dental professional can select various settings such as: ON/OFF; forward/reverse; speeds of 15, 20, or 25 rpms; and torque settings between 10 and 40 N·cm.
Statement of Intended Use:	This product is a cordless motor handpiece system intended for tightening and loosening an abutment screw to fix and remove the abutment on a dental implant in prosthodontic treatment.
Summary of Technological Characteristics:	The ON/OFF switch lever allows for easy operation. Operates continuously for approx. 1.2 hours at rated load. The load limit can be set at any value between 10 and 40 N·cm. When the load limit is reached during use, an alarm sounds. If the load limit is exceeded during use, rotation will automatically stop. Through the calibration function, torque differences between the motor handpiece and the contra-angle head can be minimized.
Performance Testing:	The iSD900 Prosthodontic Screwdriver was developed and is produced under consideration of all applicable technical standards and internal specifications. The product's conformance with the applicable technical standards and internal specifications was verified in the course of bench testing and software validation testing.
Conclusion:	Nakanishi considers the iSD900 to be substantially equivalent to the predicate device listed above. This conclusion is based on the similarities in intended use, principles of operation, functional design, and established medical use.

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DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
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Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

Nakanishi, Incorporated
C/O Ms. Rutherford
Regulatory Engineer
Ken Block Consulting
1201 Richardson Drive, Suite 280
Richardson, Texas 75080

FEB 15 2012

Re: K110278
Trade/Device Name: Cordless Prosthodontic Screwdriver with Torque Calibration System, Model iSD900
Regulation Number: 21 CFR 872.4200
Regulation Name: Dental Handpiece and Accessories
Regulatory Class: I
Product Code: EKX
Dated: January 27, 2012
Received: February 7, 2012

Dear Ms. Rutherford:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

for

Anthony D. Watson, B.S., M.S., M.B.A.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

INDICATIONS FOR USE

510(k) Number: K110278

Device Name: Cordless Prosthodontic Screwdriver with Torque Calibration System, Model iSD900

Indications for Use:

This product is a cordless motor handpiece system intended for tightening and loosening an abutment screw to fix and remove the abutment on a dental implant in prosthodontic treatment.

Prescription Use ____X____ AND/OR Over-the-Counter Use _____
(21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDHR, Office of Device Evaluation (ODE)

Susan Runner

(Division Sign-Off)
Division of Anesthesiology, General Hospital
Infection Control, Dental Devices

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